

## Medtronic Cardiac Rhythm Disease Management Guideline II Pacing Systems / 2009

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Medicare issued national guidelines<sup>1</sup> for transtelephonic monitoring of cardiac pacemakers in order to provide guidance to their local contractors for claims adjudication. These guidelines state the following:

Both the pacemaker and lead(s) must meet specific standards for longevity and end-of-life decay to be considered a Guideline II pacing system.

The standards are as follows:

- 90% cumulative survival at 5 years following implant
- An end-of-life decay of less than a 50 percent drop of output voltage and less than 20 percent deviation of magnet rate, or a drop of 5 beats per minute or less, over a period of 3 months or more

The following Medtronic devices meet these standards and are considered Guideline II pacing systems.

### Single Chamber Pacemaker Pulse Generators<sup>2</sup>

Brand Name	Model Number
Kappa <sup>®</sup> 400 SR	KSR401, KSR403
Kappa <sup>®</sup> 700 SR	KSR701, KSR703, KSR706
Kappa <sup>®</sup> 900 SR	KSR901, KSR903, KSR906
Legend <sup>®</sup>	8416, 8417, 8417M, 8418, 8419
Legend <sup>®</sup> II	8424, 8426, 8427
Micro Minix <sup>®</sup>	8360
Minix <sup>®</sup> /Minix <sup>®</sup> ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342
Pasys <sup>®</sup> /Pasys ST	8316, 8317, 8318, 8320, 8322, 8329
Preva <sup>®</sup> SR	8088, 8089
Prevail <sup>®</sup> S	8084, 8085, 8086
Prodigy <sup>®</sup> S	8164, 8165, 8166
Prodigy <sup>®</sup> SR	8158, 8160, 8161, 8162
Sigma <sup>®</sup> 100 S	SS103, SS106
Sigma <sup>®</sup> 200 SR	SSR203
Sigma <sup>®</sup> 300 SR	SSR303, SSR306
Spectrax <sup>®</sup> S	5940, 5940LP, 5941
Spectrax <sup>®</sup> SXT	8420, 8422, 8423, 8423M
Thera <sup>®</sup> -S	8944, 8945, 8946
Thera <sup>®</sup> -SR	8940, 8941, 8942
Thera <sup>®</sup> -i S	8964i, 8965i, 8966i
Thera <sup>®</sup> -i SR	8960i, 8961i, 8962i

<sup>1</sup> The Centers for Medicare and Medicaid Services (CMS) Publication 100.03, Medicare Coverage Issues Manual; National Coverage Determination (NCD) §20.8.1 and §20.8.1.1, October 1984 (Rev. October 3, 2003)

<sup>2</sup> Source: Cardiac Rhythm Disease Management Medtronic 2009 Product Performance Report, 1st Edition

## Dual Chamber Pacemaker Pulse Generators<sup>2</sup>

Brand Name	Model Number
Elite <sup>®</sup>	7074, 7075, 7076, 7077
Elite <sup>®</sup> II	7084, 7085, 7086
Kappa <sup>®</sup> 400 DR	KDR401, KDR403
Kappa <sup>®</sup> 600 DR	KDR601, KDR603, KDR606, KDR651, KDR653
Kappa <sup>®</sup> 700 DR	KDR701, KDR703, KDR706, KDR721
Kappa <sup>®</sup> 700 VDD	KVDD701
Kappa <sup>®</sup> 700 D	KD701, KD703, KD706
Kappa <sup>®</sup> 800 DR	KDR801, KDR803
Kappa <sup>®</sup> 900 VDD	KVDD901
Kappa <sup>®</sup> 900 DR	KDR901, KDR903, KDR906
Kappa <sup>®</sup> 920 DR	KDR921
Minuet <sup>®</sup>	7107, 7108
Preva <sup>®</sup> D	7068
Preva <sup>®</sup> DR	7088, 7089
Preva <sup>®</sup> ST DR	7078
Prodigy <sup>®</sup> D	7864, 7865, 7866
Prodigy <sup>®</sup> DR	7860, 7861, 7862
Sigma <sup>®</sup> 200 DR	SDR203
Sigma <sup>®</sup> 300 DR	SDR303, SDR306
Sigma <sup>®</sup> 300 VDD	SVDD303
Thera <sup>®</sup> -D	7944, 7945, 7946
Thera <sup>®</sup> -DR 40	7940, 7941, 7942
Thera <sup>®</sup> -DR 50	7950, 7951, 7952
Thera <sup>®</sup> -i D	7964i, 7965i, 7966i
Thera <sup>®</sup> -i DR	7960i, 7961i, 7962i, 7968i
Thera <sup>®</sup> -i VDD	8968i

## Triple Chamber Pacemaker Pulse Generators<sup>2</sup>

Brand Name	Model Number
InSync	8040
InSync III	8042

<sup>2</sup> Source: Cardiac Rhythm Disease Management Medtronic 2009 Product Performance Report, 1st Edition

## Ventricular Leads<sup>2</sup>

Brand Name	Model Number
CapSure <sup>®</sup>	4003, 4003M, 5026
CapSureFix <sup>®</sup>	4068, 5068
CapSureFix <sup>®</sup> Novus	5076
CapSure Sense <sup>®</sup>	4074
CapSure <sup>®</sup> SP	4023, 4024, 5023, 5023M, 5024, 5024M
CapSure <sup>®</sup> SP Novus	4092, 5092
CapSure <sup>®</sup> Z	4033, 5033, 5034
CapSure <sup>®</sup> Z Novus	5054
No brand listed	6907R
Screw-In	4016, 4057, 4057M, 4058, 4058M
Spectraflex <sup>™</sup>	6957
Target Tip <sup>®</sup>	4011, 4012, 4081, 5064
Tenax <sup>®</sup>	6961, 6962

## VDD Single Pass Pacing Lead<sup>2</sup>

Brand Name	Model Number
CapSure <sup>®</sup> VDD-2	5038

## Atrial Leads<sup>2</sup>

Brand Name	Model Number
CapSure <sup>®</sup>	4504, 4504M
CapSureFix <sup>®</sup>	4068, 4568, 5068, 5568, 6940
CapSureFix <sup>®</sup> Novus	5076
CapSure <sup>®</sup> SP	4524, 5524, 5524M
CapSure <sup>®</sup> SP Novus	4592, 5592
CapSure <sup>®</sup> Z	4533, 5534
CapSure <sup>®</sup> Z Novus	5554
Screw-In	4016, 4058, 4058M, 4557, 4557M, 4558M
Spectraflex <sup>™</sup>	6957, 6957J
SureFix <sup>®</sup>	5072
Target Tip	4511, 4512

## Epi/Myocardial Leads<sup>2</sup>

Brand Name	Model Number
Tenax <sup>®</sup>	6917, 6917A
CapSure <sup>®</sup> Epi	4968
5071	5071

<sup>2</sup> Source: Cardiac Rhythm Disease Management Medtronic 2009 Product Performance Report, 1st Edition